

Comparison study of treatment given to children with asthma by a nurse practitioner, a general practitioner or a pediatrician. (Vergelijkende studie met betrekking tot de controle van kinderen met astma door de nurse practitioner, de huisarts of de kinderarts)

Submission date 11/08/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/08/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/08/2011	Condition category Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Comparison study to follow-up of treatment given to children with stable asthma by a nurse practitioner, a general practitioner or a pediatrician: a randomized controlled trial

Acronym

TRAM

Study objectives

TRAM (TRAns mural Asthma Management). Treatment of children with stable asthma by a nurse practitioner is not inferior to treatment by a general practitioner or a pediatrician.

Ethics approval required

Old ethics approval format

Ethics approval(s)

TWOR Medical Centre "Rijnmond" South, Rotterdam approved on 11 January 2008, ref: nl. 17972.101.07

Study design

Randomized controlled trial

Primary study design

Observational

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Pediatric asthma

Interventions

Children were randomly assigned to one of the three follow up arm and at baseline, one year & two year a variety of outcome measures were collected.

1. Management by general practitioner
2. Management by paediatrician
3. Management by asthma nurse

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Inhaled corticosteroid (beta-2-agonist), PD20 methacholine

Primary outcome measure

1. Airway hyper responsiveness
 2. PD20 methacholine
- Measured at baseline, one year & two year

Secondary outcome measures

1. Forced expiratory volume in one second (FEV1) before and after bronchus dilatation with beta-2-agonist
2. Exhaled nitric oxide (NO)
3. Asthma Control Questionnaire
4. Health economics
5. Prescribed medication
6. Quality of Care assessment by completing the QUOTE-CNSLD instrument by parents
7. Completion of Likert scale by the children

Overall study start date

04/03/2005

Completion date

28/01/2009

Eligibility

Key inclusion criteria

1. Children 6-16 years
2. Moderate asthma as defined by the guideline of the dutch pediatric pulmonologists or diagnosed as asthma by their general practitioner (GP) and on prophylactic treatment with inhaled corticosteroid (ICS)

Participant type(s)

Patient

Age group

Child

Lower age limit

6 Years

Upper age limit

16 Years

Sex

Both

Target number of participants

110

Key exclusion criteria

Serious, poorly controlled asthma requiring step intravenous (IV) treatment according to the action plan in the guideline

Date of first enrolment

04/03/2005

Date of final enrolment

28/01/2009

Locations**Countries of recruitment**

Netherlands

Study participating centre**Department of Pediatrics**

Breda

Netherlands

4800 RL

Sponsor information**Organisation**

Amphia Hospital (Netherlands)

Sponsor details

Langendijk 75

Breda

Netherlands

4819 EV

Sponsor type

Hospital/treatment centre

Website

<http://www.amphia.nl/Pages/default.aspx>

ROR

<https://ror.org/01g21pa45>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Amphia Hospital (Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration